THE HONORABLE MARSHA J. PECHMAN

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

KENNETH McGUIRE, On Behalf of Himself and All Others Similarly Situated,

Plaintiffs,

v.

DENDREON CORPORATION, et al.,

Defendants.

CASE NO.: C07-800-MJP

Consolidated Class Action

DECLARATION OF MARY COON IN SUPPORT OF DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT IN *MCGUIRE V. DENDREON* AND *MOUNTANOS V. DENDREON*

Note on Motion Calendar:
July 30, 2010

ORAL ARGUMENT REQUESTED

This document relates to:

All Actions.

WILLIAM MOUNTANOS, PETER MOUNTANOS, JAMES RYE, and TYRONE REMINGA,

Plaintiffs,

v.

DENDREON CORPORATION, a Delaware Corporation, MITCHELL GOLD, and DAVID URDAL,

Defendants.

CASE NO.: C09-426-MJP

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I, Mary Coon, declare:

1. I am the Vice President of Quality for Dendreon Corporation ("Dendreon" or "Company"). I make this declaration in support of Defendants' Motion for Partial Summary Judgment in *McGuire v. Dendreon* and *Mountanos v. Dendreon*, filed concurrently herewith. I am familiar with the facts set forth herein and could and would testify thereto if necessary.

2. In February 2007, in my role as Vice President of Quality, I had primary responsibility for managing the FDA's 2007 Pre-License Inspection ("PLI") of the Company's New Jersey manufacturing facility.

3. I have over thirty years of experience in the FDA-regulated pharmaceutical industry, having previously served as Vice President of Quality and Regulatory Affairs at Bioport Corporation; Director of Quality Services at Perrigo Company; Director of Quality for the Western Division at Leiner Health Products, Inc.; and in various quality positions at Miles, Inc. During my career, I have been involved in over 20 FDA inspections and numerous other third-party inspections. Since the early 1990s, every inspection I have been involved in has resulted in a Form 483. I expected Dendreon to receive a Form 483 following the PLI because it is the standard expectation within the industry. Simply put, most inspections result in the receipt of a Form 483.

4. I advised the members of Dendreon's executive team, including Dr. David Urdal, Chief Scientific Officer, and Dr. Mitchell Gold, Chief Executive Officer, that they should expect a Form 483 following the PLI. Based on my experience and the fact that a new product and a new facility were involved, I was not at all surprised or disappointed when Dendreon received a Form 483.

5. I believe Dendreon hosted a good inspection. We performed well in the areas of leadership, logistical management, and managing technical and scientific data. Logistical management involves ensuring that rooms and subject matter experts are available; that all documents reflecting a company's processes are available and ready for review; that responses to inspector requests are prompt; that each day's agenda is communicated in a transparent manner;

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and that inspectors see the processes that they want to evaluate. Managing technical and scientific data means being able to explain and answer questions about any data at the request of the FDA inspectors.

6. The Form 483 is a testament to the success of our inspection, because it did not contain any observations that were "showstoppers," or to which we could not respond in a timely and effective way. Ex. 22 (2007 Form 483).

7. I attended the closeout meeting with the FDA inspectors at the conclusion of the inspection. As my notes reflect, the FDA inspectors made many positive comments during this meeting. Ex. 14 (notes from Feb. 16, 2007 closeout meeting with the FDA). FDA reviewer Dr. Gang Wang said that the inspectors were well received and that it was a "good experience" for them, and said that the purpose of the Form 483 was to bring issues to our attention, so that we could respond in a timely manner. Dr. Keith Wonnacott, the FDA's lead product reviewer for Provenge, said he thought the organization was "excellent," as was the flow of information and communication, and told us that we would have a chance to respond to each of the Form 483 observations. FDA inspector Dr. Tom Finn said he was "very impressed" by the individuals in manufacturing and quality control, and that while the FDA found some issues, overall he felt that we were "very qualified." Dr. Wonnacott concluded by telling us that Provenge was important to the FDA and to the industry.

8. In my experience, FDA facility inspectors are forthright in their comments to company representatives, and if they believed that the PLI had revealed serious problems that would prohibit licensure, they would have told us so. At no point during the closeout meeting did the FDA inspectors say or imply that any of the Form 483 observations would prevent the approval of Provenge in 2007.

9. I spoke with Dr. Urdal, Ernie Bognar, then Plant Manager of the New Jersey facility, and Andrew Scherer, Dendreon's Vice President of Manufacturing, with some frequency during and after the PLI. My team and I relayed to Dr. Urdal that the inspection was going well, that the logistics were smooth, that the delivery of materials and information to the FDA was

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sound, that Dendreon staff members were available to respond to the FDA's questions, and that Dendreon responded completely to the FDA's requests. Dr. Urdal told me that he thought Dendreon had done an excellent job during the inspection. Mr. Bognar and Mr. Scherer expressed to me that they thought the inspection was successful and we handled the logistics of the inspection well.

10. Dendreon responded to the Form 483 observations quickly in order to assure the FDA inspectors of our commitment to resolving the observations, and so that we could get feedback from the FDA on our action plan to resolve the observations. I believe that we had either completed, or made arrangements with the FDA to complete, all of our commitments to respond to the Form 483 observations, in time for approval by the May 15, 2007 PDUFA date.

11. We discussed our responses to the Form 483 observations and came to agreement with the FDA on our proposed action plan during a series of conference calls after the PLI. During a March 23, 2007 conference call, as my notes reflect, Dr. Wonnacott said the FDA wanted to inform us that because one of our initial responses to the Form 483 observations included the submission of additional data, the FDA would consider it to be a major amendment (which would thus push back the PDUFA date). Ex. 30 (notes from March 23, 2007 conference call). Dendreon Vice President of Regulatory Affairs Elizabeth Smith told the FDA that Dendreon would be willing to accept an initial limit on manufacturing capacity in order to gain approval by the PDUFA date, and then submit additional data following approval to lift those limits. Dr. Wonnacott indicated that the FDA would consider that proposal, and suggested that a conference call be held after the upcoming FDA Advisory Committee meeting to discuss the details of Dendreon's proposal. My impression of this exchange was that the FDA was open to our proposal. Significantly, Dr. Wonnacott also told us that our other eight responses to the Form 483 observations would require only minor amendments.

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge. Executed in Seattle, Wa, on 6.21.10.

Mary Coon

Mary Coon

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CERTIFICATE OF SERVICE

I hereby certify that on June 21, 2010, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record who receive CM/ECF notification.

Dated: June 21, 2010

s/ Barry M. Kaplan
Barry M. Kaplan, WSBA#8661

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